DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

MAR 2 2000

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Timothy J. Maher, Ph.D.
Massachusetts College of Pharmacy and Health Sciences
Boston, MA 02115

Richard J. Wurtman, M.D.
Massachusetts Institute of Technology
Cambridge, MA 02139

Re: Docket No. 99P-4053/CP/1

Dear Doctors Maher and Wurtman:

I am writing to inform you that the Food and Drug Administration has not yet resolved the issues raised in your citizen petition submitted to the Dockets Management Branch on September 13, 1999, and supplemented on November 9, November 16, and December 20, 1999. Your petition requests that the Agency amend required product labeling and the patient insert for the sympathomimetic amine phentermine (in all salt forms) to indicate that it inhibits the enzyme monoamine oxidase and should be classified as a monoamine oxidase inhibitor.

FDA has been unable to reach a decision on your petition due to the need to address other Agency priorities. This interim response is provided in accordance with FDA regulations on citizen petitions (21 CFR 10.30(e)(2)). We will respond to your petition as soon as possible given the numerous demands on the Agency's resources.

Sincerely yours,

Janet Woodcock, M.D.
Director
Center for Drug Evaluation and Research

99P-4053

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